

### **REMARKS**

This paper is filed in response to the Office Action mailed October 9, 2007. The above-amendments cancel claims 1-12 and 16. Applicants reserve the right to pursue the canceled claims in a divisional application. Furthermore, claim 13 has been amended to be directed to a method of treating a patient with tissue engineered material comprising: administering a peptide-amphiphile composition to a site of a patient in need thereof, said peptide-amphiphile composition capable of stimulating or inhibiting a plurality of biological signals at said site and capable of forming a nanofiber network, wherein said peptide-amphiphile composition contains a peptide amphiphile composition comprises SEQ ID NO:1 or SEQ ID NO:2. Claims 14 and 15 and new claims 17 and 18 depend from claim 13 and further describe the composition of claim 13. The specification, for example, supports SEQ ID NOS:1 and 2 in Table 1; outgrowth the axon outgrowth at paragraph [0018]; the composition comprising SEQ ID NO:1 and 2 in Example 1, paragraphs [0045]-[0049]; the concentration range is supported in paragraph [0034]; the charge equivalent ratio is supported in paragraph [0033]; and the ratio of claim 18 is supported in paragraph [0048]. No new matter has been added by these amendments and entry of these amendments is respectfully requested.

#### *Sequence Rules Compliance*

The Examiner states that the specification and Figures contain sequences with four or more consecutive amino acid without any corresponding SEQ ID NO and/or no reference to any SEQ ID NO in the Brief Description of the Drawings. Applicants have amended the specification to comply with the sequence rules.

#### *35 USC 112, Second Paragraph*

Claims 13-15 are rejected under 35 USC 112, second paragraph, as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter, which Applicants regard as the invention. It is stated that the claims do not state that the administration must occur to a patient in need thereof and, therefore, the claims are indefinite. Applicants have amended independent claim 13 to recite that administration is

made to a site on a patient in need thereof. Withdrawal of the rejection is respectfully requested.

*35 USC 112, First Paragraph*

Claims 13-15 are rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. It is stated that the claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office Action states that there are only two representative species, Molecules 1 and 2 of Figure 1, for the claimed genus. The Action states that disclosure of two species does not show that Applicants are in possession of the claimed genus.

Applicants respectfully disagree. However, in order to expedite the prosecution of this application, Applicants have amended independent claim 13 to specify that the claim-designated composition contains a peptide amphiphile containing SEQ ID NO:1 or SEQ ID NO:2. In view of the foregoing amendment, withdrawal of the rejection is respectfully requested.

Claims 13-15 are rejected under 35 USC 112, first paragraph, because the specification allegedly does not reasonably provide enablement for a method of treating a patient in need by administering a plurality of undefined peptide-amphiphiles, which act to stimulate or inhibit a plurality of any biological signals and also form a nanofiber network. The Office Action states, however, that Molecules 1 and 2 are enabled for methods of treating a patient in need thereof by administering Molecule 1 to stimulate axon outgrowth in neurons and Molecules 1 and 2 to promote cell-substrate adhesion in nerve cells. Applicants have amended independent claim 13 to be directed to a method of treating a patient with a tissue engineered material by the administration of SEQ ID NO:1 or SEQ ID NO:2 to said patient. The amended claim further recites that the composition containing the peptide amphiphile of SEQ ID NO:1 or SEQ ID NO:2 is capable of promoting axon outgrowth of neurons in the patient. Accordingly, Applicants respectfully submit that the rejection is obviated and withdrawal of the rejection is respectfully requested.

*35 USC 102*

Claim 13 is rejected under 35 USC 102(e) as allegedly being anticipated by Kisiday et al. (US 2002/0160471). Kisiday is stated to teach various peptide amphiphiles, which self-assemble into a beta-sheet macroscopic scaffold. The reference is stated to teach administering the macroscopic scaffold to mammals for tissue regeneration, wherein the peptide amphiphile scaffold also possesses cell signals such as RGD to promote proliferation of the encapsulated cells.

Applicants respectfully traverse the rejection. The amended claim 13 is directed to a method of treating a patient with tissue engineered material comprising: administering a peptide-amphiphile composition to a site of a patient in need thereof, said peptide-amphiphile composition capable of promoting axon outgrowth of a neuron, wherein said peptide-amphiphile composition contains a peptide amphiphile composition comprising SEQ ID NO:1 or SEQ ID NO:2. Kisiday does not teach using a composition comprising either SEQ ID NO:1 or SEQ ID NO:2. Accordingly, Kisiday does not teach each and every element of the claim. Withdrawal of the rejection under 35 USC 102(e) is proper.

*35 USC 103*

Claims 13-15 are rejected under 35 USC 103 as being obvious over Stupp et al (US 20040001893). The Stupp application is stated to teach a peptide amphiphile composition comprising two peptide amphiphiles, wherein the first peptide amphiphile possesses a net charge at a physiological sequence and the second peptide amphiphile comprises an opposite charge compared to the first peptide amphiphile at the same pH. However, the Stupp application is stated not to describe the administration of the composition to a patient for tissue engineering. The Office Action states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the Stupp composition for tissue engineering because "the composition is taught that it was designed in part for this purpose and has advantages such as being able to affect more than one biological signal as other peptide amphiphile[] compositions do." (Office Action at 16.) Applicants respectfully traverse the rejection.

Applicants have amended independent claim 13 to use a claim-designated composition having a peptide amphiphile containing either SEQ ID NO:1 or SEQ ID NO:2. Applicants respectfully submit that the Stupp application cited in the instant rejection does not describe or suggest either of these two molecules. Accordingly, withdrawal of the instant rejection is proper and respectfully requested.

*Conclusion*

Applicants believe that the instant application is in condition for allowance. However, in the event that Examiner disagrees, she is invited to call the undersigned any outstanding issues to expedite the prosecution of this application.

Respectfully submitted,

BENET GROUP LLC

/Maria L. Maebius/

Maria L. Maebius  
Registration No. 42,967

c/o Intellevate  
P.O. Box 52050  
Minneapolis, MN 55402  
Tel. 202.253.7199  
Fax 612-677-3572  
Date: 10 March 2008